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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/565,810
Filing Date: February 09, 2006
Appellant(s): NEFTEL ET AL.

Neftel, Frederic; Junod, Florent; Vecten, Didier
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 15 December 2010 appealing from the Office action mailed 18 March 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-9, and 11-66 are pending in the application.

Claims 1-9, and 11-66 were rejected in the application.

Claim 10 was cancelled during prosecution.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except

for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

2,684,829	McFarland	7-1954
4,530,647	Uno	7-1985
4,586,920	Peabody	5-1986
4,758,228	Williams	7-1988
4,828,545	Epstein	5-1989
4,952,372	Huber	8-1990
5,350,357	Kamen et al.	9-1994
5,437,629	Goldrath	8-1995
5,478,211	Dominiak et al.	12-1995
5,518,378	Neftel et al.	5-1996
5,683,233	Moubayed et al.	11-1997
5,840,069	Robinson	11-1998
EP 1195171 A2	Suzuki	4-2002
5722947	Jeppsson et al.	3-1998

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 2, 8, 9, 17, 19-21, 26, 30, 41-45, 48, 54, 56-58, 61, 64, 65, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,350,357 to Dean Kamen, et al., (Kamen) in view of U.S. Patent No. 5,518,378 to Frederic Neftel et al. (Neftel).

In regards to claim 1, Kamen teaches a system for performing fluid administration on a patient comprising a liquid distribution system that is a cartridge (Fig. 3, #24) and that is separate from said pump and that is connected to said pump in such a way that liquid can flow from the liquid distribution system to the pump and vice versa (col. 7, lines 52-54 – the pump is separate from the liquid distribution system by the walls of the pump chamber, otherwise the pump would not work if exposed to the liquid distribution system), liquid supply means (Fig. 1, #36) for supplying liquid to a patient via said liquid distribution system and said pump, a patient conduit (Fig. 1, #18) adapted for connecting said liquid distribution system to a patient, wherein said liquid distribution system comprises two distinct hub chambers which are separated by a space, the first hub chamber (Fig. 8A, #F9) including at least one liquid supply port (Fig. 8A, #33) with dedicated valve means (Fig. 8A, #V6), one patient port (Fig. 8A, # 35) with dedicated

valve means (Fig. 8A, #V7) and one pump inlet (Fig. 8A, #66(2)), the second hub chamber (Fig. 8A, #F8) including at least, one patient port (Fig. 8A, #35)) or warmer port with dedicated valve means (Fig. 8A, #V8) and one pump outlet (Fig. 8A, #66(1)), said system furthermore comprising control means arranged to close said patient port of the first hub chamber (Fig. 33, #V7) when said liquid supply port (Fig. 8A, #33) is open and vice versa (Fig. 8A, #V6, V8), and wherein all ports of the liquid distribution system that communicate with the pump are unidirectional such that liquid only flows in one direction (col. 35, lines 4-12, 32-40 – shows that the valves V7 and V8 are opened in one direction during pumping).

Kamen does not teach a partial peristalitic pump.

Neftel teaches a partial peristaltic pump (Fig. 5, #1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have replaced the reciprocating pump of Kamen with the partial peristaltic pump of Neftel in order to prevent the pump from becoming contaminated (col. 2, lines 64-67) as taught by U.S. Patent 5,722,947 to Jan-Bertil Jeppsson et al. (Jeppsson).

In regards to claims 2, 8, 9, 17, 19-21, 26, 30, 41-45, 48, 54, 56-58, 61, 64, 65, Kamen, as modified by Neftel, teaches the system according to claim 1, where Kamen further teaches:

Claim 2: said second hub chamber (Fig. 8A, #F8) furthermore includes at least one drain port (Fig. 8A, #29) with dedicated valve means (Fig. 8A, #V4), said control means being also arranged to close said patient port (Fig. 8A, #35) of the second hub chamber (Fig. 8A, #F8) when said drain port (Fig. 8A, #29) is open and vice versa;

Claim 8: said first hub chamber (Fig. 8A, #F9) includes several liquid supply ports (Fig. 8A, #31, 33) with respective valve means (Fig. 8A, #V5, V6);

Claim 9: said liquid supply ports (Fig. 8A, #31, 33) are connected to respective liquid supply means having each a different kind of liquid (Fig. 1, #20 & col. 35, lines 65-68);

Claim 17: said pump (Fig. 8A, #P1, P2) and said liquid distribution system (Fig. 8A, #24) are fixed together to form a single cartridge (col. 7, lines 43-46);

Claim 19: wherein all hub chambers, including said ports and ports, are made within one single part (col. 7, lines 37-38, 43-44);

Claim 20: Claim 20 is a product-by-process claim. This claim is not limited to manipulations of the recited steps, only the structure implied by the steps. The patentability of a product does not depend on its method of production. See MPEP 2113.

said single part is an injected part of plastic material (col. 7, lines 37-38);

Claim 21: each hub chamber (Fig. 8A, #F9, F8) is closed with an upper wall made of a flexible membrane (Fig. 8, #59, 61), said membrane including valve elements (Fig. 8C, #V_N) situated above each of said port or port with valve means (Fig. 8C, #68), said valve elements (Fig. 8C, #V_N) being designed to close said port or port when the membrane (Fig. 8C, #59, phantom lines) moves downwardly;

Claim 26: said membrane extends in such a way that it also covers said pump (Fig. 8, #59, 61);

Claim 30: said liquid distribution system (Fig. 8A, #24) includes liquid tight joints (Fig. 8C, #f) arranged in such a manner that they allow a liquid tight connection between said liquid distribution system and a membrane situated on it (col. 7, lines 40-42);

Claim 41: comprising a cartridge loading mechanism (col. 12, lines 65-68 and col. 13, lines 1-2) which allows a tight connection between the membrane (col. 13, lines 3-4) and the valves (col. 13, lines 17-21) and the liquid distribution system (Fig. 15B, #24);

Claim 42: comprising flow blocking means (Fig. 16A, #144, 148) adapted to block the flow towards or from the liquid distribution system (col. 14, line 59) when this latter one is released out of the system (col. 14, lines 49-50);

Claim 43: said blocking means is a mechanical clamp situated on the patient line (Fig. 1, #40);

Claim 44: said blocking means is a lip valve (Fig. 16A, #144, 148) situated on the patient line (col. 14, line 59), the system furthermore comprises a movable pin (Fig. 16B, #138) adapted to open said lip valve when the liquid distribution system is released out of the system col. 14, lines 25-29);

Claim 45: comprising a molded frame (Fig. 13, #102) adapted to cover the space between said hub chambers (Fig. 13, #122), each space above said hub chambers being covered by a flexible membrane (Fig. 8, #59, 61);

Claim 48: Claim 48 is a product-by-process claim. This claim is not limited to manipulations of the recited steps, only the structure implied by the steps. The

patentability of a product does not depend on its method of production. See MPEP 2113.

said frame (Fig. 13, #102), membrane (Fig. 8, #59, 61) and liquid distribution system (Fig. 8A, #24) are obtained by overmolding technique;

Claim 54: a liquid distribution system (Fig. 8A, #24) for a system performing fluid administration on a patient (col. 38, line 1) as defined in claim 1;

Claim 56: method of use of the system as defined in claim 1 (see rejection above) wherein said patient port (Fig. 33, V7) is closed when said liquid supply port (Fig. 33, #33) is open and vice versa (Fig. 34, #V6, V8);

Claim 57: method according to claim 56 (see rejection above) wherein the pressure is always maintained positive with respect to the drain (col. 2, lines 66-68 – col. 3, lines 1-2);

Claim 58: method according to claim 56 (see rejection above) wherein said liquid is always pumped in the same direction (col. 2, lines 58-63);

Claim 61: Method according to claim 56 (see rejection above) wherein the drain phase is a function of the drain speed (col. 34, lines 45-51), said drain phase being ended when the speed is reaching a certain value based on the patient peritoneal cavity pressure measurement (col. 35, lines 55-57);

Claim 64: Method according to claim 56 (see rejection above) consisting in the use of a low Natrium concentration liquid for the last exchange cycle to improve ultra-filtration (col. 35, lines 65-68 - col. 36, lines 1-2).

Changing the dextrose concentration is known to increase ultrafiltration, similar to changing the Natrium concentration but without the increase in ionic concentration of the solution, which could lead to alterations in the electrical properties of the cells of the peritoneum;

Claim 65: Use of a system as defined in claim 1 (see rejection above) for peritoneal dialysis (col. 38, line 1) comprising selecting a liquid (Fig. 32 – shows a selected liquid in a heater bag), supplying the liquid to a patient via use of the system for peritoneal dialysis (Fig. 32 – shows the system pumping fluid from the heater bag to the patient catheter).

In regards to claim 66, Kamen teaches a disposable cassette for use in performing fluid administration on a patient comprising a liquid distribution system in a substantially rectangular-shaped member (Fig. 8A, #24) that is separate from said pump and that is abutted to a side of said pump in such a way that liquid can flow from the liquid distribution system to the pump and vice versa (col. 7, lines 52-54 – the pump is separate from the liquid distribution system by the walls of the pump chamber, otherwise the pump would not work if exposed to the liquid distribution system), liquid supply means (Fig. 1, #36), a patient conduit (Fig. 1, #18), wherein said liquid distribution system comprises a first hub chamber (Fig. 8A, #F9) and a distinct second hub chamber (Fig. 8A, #F8) which are separated by a space (Fig. 8A – shows the chambers are separated by the walls of the cassette), the first hub chamber including at least one liquid supply port (Fig. 8A, #33) with dedicated valve means (Fig. 8A, #V6), one patient port (Fig. 8A, # 35) with dedicated valve means (Fig. 8A, #V7) and one pump inlet (Fig. 8A, #66(2)), the

second hub chamber including at least one patient port (Fig. 8A, #35)) or warmer port with dedicated valve means (Fig. 8A, #V8) and one pump outlet (Fig. 8A, #66(1)), said system further comprising control means arranged to close said patient port (Fig. 33, #V7) of the first hub chamber when said liquid supply port (Fig. 8A, #33) is open and vice versa (Fig. 8A, #V6, V8), and wherein all ports of the liquid distribution system that communicate with the pump are unidirectional ports (col. 35, lines 4-12, 32-40 – shows that the valves V7 and V8 are opened in one direction during pumping).

Kamen does not teach a partial peristaltic pump.

Neftel teaches a partial peristaltic pump (Fig. 5, #1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have replaced the reciprocating pump of Kamen with the partial peristaltic pump of Neftel in order to prevent the pump from becoming contaminated (col. 2, lines 64-67) as taught by Jeppsson.

3. Claims 3-5, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen, as modified by Neftel, as applied to claim 1 above, and further in view of U.S. Patent 5,437,629 to Milton H. Goldrath (Goldrath).

In Reference to Claim 3

Kamen, as modified by Neftel, teaches:

A system according to claim 1 (see rejection above) wherein said liquid distribution system (Fig. 8A, #24)

However, Kamen, as modified by Neftel, does not teach:

said liquid distribution system only includes two hub chambers.

Goldrath teaches:

said liquid distribution system only includes two hub chambers (Fig. 2, #12, Fig. 3, #37 & col. 5, lines 37-39).

It would have been obvious to one skilled in the art at the time of the invention to have used the chambers of Goldrath in the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to collect the drained solution (col. 3, lines 17-18) implicitly taught by Goldrath.

In Reference to Claim 4

Kamen, as modified by Neftel, teaches:

A system according to claim 1 (see rejection above) furthermore comprising a warmer system (Fig. 9, #74),...

said patient port (Fig. 8A, #35) of the second hub chamber (Fig. 8A, #F8) being connected to said warmer port (Fig. 8A, #27) via said warmer system (Fig. 9, #74).

However, Kamen, as modified by Neftel, does not teach:

a cavity including a warmer port and a patient port

Goldrath teaches:

a cavity (Fig. 2, #24) including a warmer port (Fig. 2, #22) and a patient port (Fig. 2, #26).

It would have been obvious to one skilled in the art at the time of the invention to have included the warmer port and cavity of Goldrath in the peritoneal dialysis apparatus of

Kamen, as modified by Neftel, in order to maintain the solution at the desired temperature (col. 2, line 68 - col. 3, line 1).

In Reference to Claim 5

Kamen, as modified by Neftel, teaches:

A system according to claim 4 (see rejection above) wherein said warmer system (Fig. 9, #74)

However, Kamen, as modified by Neftel, does not teach:

is a warmer in-line.

Goldrath teaches:

is a warmer in-line (col. 6, lines 21-22).

It would have been obvious to one skilled in the art at the time of the invention to have put the warmer of Goldrath in-line with the infusion pathway of Kamen, as modified by Neftel, in order to heat the solution as needed and reduce setup time.

In Reference to Claim 11

Kamen, as modified by Neftel, teaches:

A system according to claim 1 (see rejection above)

However, Kamen, as modified by Neftel, does not teach:

wherein said peristaltic pump is unidirectional.

Goldrath teaches:

wherein said peristaltic pump is unidirectional (col. 4, lines 23-27).

It would have been obvious to one skilled in the art at the time of the invention to have used the peristaltic pump of Goldrath in the peritoneal dialysis apparatus of Kamen, as

modified by Neftel, in a unidirectional manner in order to prevent backflow of dialysis solution into the patient as implicitly taught by Kamen.

4. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen, as modified by Neftel and Goldrath, as applied to claim 5 above, and further in view of European Patent Application Publication EP 1 195 171 A2 to Suzuki, Minoru et al. (Suzuki).

In Reference to Claim 6

Kamen, as modified by Neftel, teaches:

A system according to claim 5 (see rejection above)

However, Kamen, as modified by Neftel, does not teach:

wherein said warmer in-line comprises a warming plate contained therein, such warming plate being covered by a warming pouch.

Suzuki teaches:

wherein said warmer in-line comprises a warming plate (Fig. 7, #91, 92, 93) contained therein, such warming plate being covered by a warming pouch like a sock.

It would have been obvious to one skilled in the art at the time of the invention to have included the warming plates of Suzuki in the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to improve heating efficiency of the dialysis fluid (col. 12, lines 50-52) as explicitly taught by Suzuki.

In Reference to Claim 7

Kamen, as modified by Neftel, teaches:

A system according to claim 6 (see rejection above)

However, Kamen, as modified by Neftel, does not teach:

> wherein said warming pouch is composed of a liquid channel which forces the liquid to be maintained within such warmer for a certain duration at a given flow rate.

Suzuki teaches:

> wherein said warming pouch is composed of a liquid channel (Fig. 7, #831, 832) which forces the liquid to be maintained within such warmer for a certain duration at a given flow rate (col. 8, lines 25-28).

It would have been obvious to one skilled in the art at the time of the invention to have included the meandering liquid channel of Suzuki in the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to reliably heat the dialysis fluid (col. 8, lines 27-28) as explicitly taught by Suzuki.

5. Claims 40, 47, 49, 51, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen, as modified by Neftel, as applied to claim 1 above, and further in view of Suzuki.

In Reference to Claim 40

Kamen, as modified by Neftel, teaches:

> A system according to claim 1 wherein said liquid distribution system (Fig. 8A, #24)

However, Kamen, as modified by Neftel, does not teach:

> includes an air sensor situated on the patient conduit side.

Suzuki teaches:

includes an air sensor (Fig. 2, #14) situated on the patient conduit side (Fig. 2, #33 & col. 13, lines 17-19).

It would have been obvious to one skilled in the art at the time of the invention to have added the air sensor of Suzuki to the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to detect "bubbles on the inlet" side (col. 13, lines 18-19) as explicitly taught by Suzuki.

In Reference to Claim 47

Kamen, as modified by Neftel, teaches:

A system according to claim 45 (see rejection above) wherein said molded frame (Fig. 13, #102)

However, Kamen, as modified by Neftel, does not teach:

the frame is at least partially made of silicone or polyurethane.

Suzuki teaches:

the frame is at least partially made of silicone or polyurethane (col. 9 lines 56-58 and col. 10, lines 1-10).

It would have been obvious to one skilled in the art at the time of the invention to have chosen the material of Suzuki for the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to improve the quality and reduce the costs of the cassette (col. 9, lines 38-40) as explicitly taught by Suzuki.

In Reference to Claim 49

Kamen, as modified by Neftel, teaches:

A system according to claims 21 (see rejection above)

However, Kamen, as modified by Neftel, does not teach:

using a double layer membrane adapted to prevents spallation or particule release into the fluid during use.

Suzuki teaches:

using a double layer membrane (col. 10, lines 10-12) adapted to prevents spallation or particule release into the fluid during use.

It would have been obvious to one skilled in the art at the time of the invention to have used the double layer membrane of Suzuki in the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to improve the quality of the cassette as implicitly taught by Suzuki.

In Reference to Claim 51

Kamen, as modified by Neftel, teaches:

A system according to claim 21 (see rejection above) ... which covers and holds the membrane (Fig. 8, #59, 61),

However, Kamen, as modified by Neftel, does not teach:

furthermore comprising a rigid plate ... said rigid plate comprising holes adapted to let moving elements passing through.

Suzuki teaches:

furthermore comprising a rigid plate (Fig. 4, #812) ... said rigid plate (Fig. 4, #812) comprising holes (Fig. 5, 81b) adapted to let moving elements passing through (col. 10, lines 15-18).

It would have been obvious to one skilled in the art at the time of the invention to have included the rigid plate of Suzuki in the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to allow reliable and easy loading of a cassette by anyone (col. 3, lines 26-28) as explicitly taught by Suzuki.

In Reference to Claim 52

Kamen, as modified by Neftel, teaches:

A system according to claim 51 (see rejection above)

However, Kamenn as modified by Neftel, does not teach:

wherein said rigid plate includes pins situated on the membrane side, said pins being adapted to be fixed

Suzuki teaches:

wherein said rigid plate (Fig. 4, #812) includes pins (Fig. 4) situated on the membrane side (Fig. 4, #811), said pins being adapted to be fixed (col. 9, lines 15-17) on the liquid distribution system (Kamen Fig. 8A, #24).

It would have been obvious to one skilled in the art at the time of the invention to have included the pins of Suzuki in the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to secure the fluid distribution system in a cassette unit as implicitly taught by Suzuki.

6. Claims 12, 35-39, 50, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen, as modified by Neftel, as applied to claim 1 in further view of U.S. Patent No. 4,758,228 to David R. Williams (Williams).

In Reference to Claim 12

Kamen, as modified by Neftel, teaches:

> A system according to claim 1 (see rejection above) wherein said liquid pump (Fig. 8A, #P1, P2)

However, Kamen, as modified by Neftel, does not teach:

> the liquid pump is composed of a tubing and rolling surface on which the tubing is compressed once the cartridge is inserted into a pumping device containing rollers.

Williams teaches:

> the liquid pump is composed of a tubing (Fig. 2A, #36) and rolling surface on which the tubing is compressed (Fig. 2A, #46) once the cartridge is inserted into a pumping device containing rollers (col. 4, lines 53-56).

It would have been obvious to one skilled in the art at the time of the invention to have included the peristaltic pump of Williams in the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to provide a peristaltic pump where variations in the administration set are minimized (col. 2, lines 9-12) as explicitly taught by Williams.

In Reference to Claim 35

Kamen, as modified by Neftel, teaches:

> A system according to claim 21 (see rejection above) wherein said membrane (Fig. 8, #59, 61)

However, Kamen, as modified by Neftel, does not teach:

> said membrane contains a portion which is forming part of a pressure sensor.

Williams teaches:

said membrane contains a portion (Fig. 10, #140) which is forming part of a pressure sensor (col. 3, lines 4-5).

It would have been obvious to one skilled in the art at the time of the invention to have included the pressure sensor of Williams in the membrane of Kamen, as modified by Neftel, in order to provide an inexpensive and very accurate pressure sensor (col. 2, lines 13-15) as explicitly taught by Williams.

In Reference to Claim 36

Kamen, as modified by Williams, teaches:

A system according to claim 35 (see rejection above)

With Williams further teaches the limitation of:

wherein the active area of said pressure sensor (Fig. 11A, #168A & Fig. 11B, #168B) is designed to be more flexible than the remaining area (col. 8, lines 55-58).

It would have been obvious to one skilled in the art at the time of the invention to have included the pressure sensor of Williams in the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to provide very accurate pressure sensor (col. 2, lines 13-15) in cassette as explicitly taught by Williams.

In Reference to Claim 37

Kamen, as modified by Williams, teaches:

A system according to claim 35 (see rejection above)

With Williams further teaches the limitation of:

wherein said pressure sensor has the shape of a disc (Fig. 10, #148, 150) of which the periphery is gripped (Fig. 11B, #168B), said disc furthermore comprising an annular ply (Fig. 10, #148, 150).

It would have been obvious to one skilled in the art at the time of the invention to have included the disc shape of Williams in the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to sense pressure in a circular tube as implicitly taught by Williams.

In Reference to Claim 38

Kamen, as modified by Williams, teaches:

A system according to claim 35 (see rejection above)...independently from said hub chambers (Fig. 8A, #F9, F8).

With Williams further teaches the limitation of:

wherein said pressure sensor is situated on the patient line (col. 7, lines 58-63)

It would have been obvious to one skilled in the art at the time of the invention to have included a pressure sensor on the patient line of Williams in the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to indicate to the operator or to signal an alarm (col. 3, lines 16-17) as explicitly taught by Williams.

In Reference to Claim 39

Kamen, as modified by Williams, teaches:

A system according to claim 35 (see rejection above)

With Williams further teaches the limitation of:

comprising a second pressure sensor (Fig. 10, #148), said second pressure sensor being in connection with the first hub chamber (Fig. 13, #144B, 146B).

It would have been obvious to one skilled in the art at the time of the invention to have added a pressure sensor of Williams on the first hub chamber of Kamen, as modified by Neftel, in order to indicate to the operator or signal an alarm (col. 3, lines 16-17) as explicitly taught by Williams.

In Reference to Claim 50

Kamen, as modified by Neftel, teaches:

A system according to claim 1 (see rejection above)

However, Kamen, as modified by Neftel, does not teach:

furthermore comprising a window for detecting correct positioning of the tube.

Williams teaches:

furthermore comprising a window for detecting correct positioning of the tube (col. 2, lines 32-38 & col. 10, lines 32-37).

It would have been obvious to one skilled in the art at the time of the invention to have included the window of Williams in the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to ensure correct installation of the cassette as implicitly taught by Williams.

It is inherent that when installing the tube and then rotating the pump knob to return the rollers to the pumping position the "first cutout" could function as window.

In Reference to Claim 55

Kamen, as modified by Williams teaches:

for a system for performing fluid administration on a patient (Kamen col. 38, line 1) as defined in claim 35 (see rejection above).

With Williams further teaches the limitation of:

a pressure sensor (Fig. 10, #140)

It would have been obvious to one skilled in the art at the time of the invention to have further added the pressure sensor of Williams to the peritoneal dialysis apparatus of Kamen, as modified by Neftel and Williams, in order to indicate to the operator or to signal an alarm (col. 3, lines 16-17) as explicitly taught by Williams.

7. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen, as modified by Neftel, as applied to claim 1 above, in further view of U.S. Patent No. 5,683,233 to Ahmad-Maher Moubayed et al. (Moubayed).

In Reference to Claim 15

Kamen, as modified by Neftel, teaches:

A system according to claim 1 wherein said pump (Neftel Fig. 5, #1)

However, Kamen, as modified by Neftel, does not teach:

the liquid pump comprises a flexible or partially flexible channel and a series of movable finger elements successively situated above said channel, each finger element being movable along a direction which is substantially perpendicular to said channel, all finger elements being adapted to induce a peristaltic movement along said channel.

Moubayed teaches:

the liquid pump comprises a flexible or partially flexible channel (Fig. 1, #28) and

a series of movable finger elements successively situated above said channel (Fig. 1, #48), each finger element being movable along a direction which is substantially perpendicular to said channel (Fig. 1), all finger elements being adapted to induce a peristaltic movement along said channel (col. 2, lines 49-62).

It would have been obvious to one skilled in the art at the time of the invention to have added the linear peristaltic pump of Moubayed in the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to "accommodate a greater range of tube wall thicknesses (col. 2, lines 24-25) as explicitly taught by Moubayed.

In Reference to Claim 16

Kamen, as modified by Neftel, teaches:

A system according to claim 15 (see rejection above)

However, Kamen, as modified by Neftel, does not teach:

wherein each finger element comprises a convex basis adapted to conform with the channel inner surface and a shaft adapted to be linked to an actuator.

Moubayed teaches:

wherein each finger element comprises a convex basis (Fig. 2, #62) adapted to conform with the channel inner surface (col. 3, lines 53-55) and a shaft adapted to be linked to an actuator (Fig. 1, #48).

It would have been obvious to one skilled in the art at the time of the invention to have included the rounded pinch finger of Moubayed in the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to "substantially eliminate damage to the tube" (col. 2, line 26) as explicitly taught by Moubayed.

8. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen, as modified by Neftel and Williams, as applied to claim 12 above, and further in view of Moubayed.

In Reference to Claim 27

Kamen, as modified by Williams, teaches:

> A system according to claim 12 (see rejection above) wherein said liquid pump (Fig. 8A, #P1, P2)

But does not teach the liquid pump comprises a flexible or partially flexible channel, a membrane covering said channel along an oblique plane, preferably at 45°, in order to allow a peristaltic movement induced by rollers or similar elements.

Moubayed teaches:

> comprises a flexible or partially flexible channel (Fig. 1, #28), a membrane covering said channel along an oblique plane (col. 3, line 26), preferably at 45°, in order to allow a peristaltic movement induced by rollers or similar elements (col. 2, 49-62).

It would have been obvious to one skilled in the art at the time of the invention to have included the flexible channel and membrane of Moubayed in the peritoneal dialysis apparatus of Kamen, as modified by Neftel and Williams, in order to avoid wall erosion or spallation causing particulate matter to end the fluid stream as implicitly taught by Moubayed. The membrane covers the channel and is along an oblique plane since the tube passes through a curvilinear peristaltic pump race.

In Reference to Claim 28

Kamen, as modified by Williams, teaches:

A system according to claim 27 (see rejection above)

But does not teach a system comprising individual actuators or a cam adapt to induce a peristaltic movement.

Moubayed teaches:

comprising individual actuators (Fig. 1, #48) or a cam (Fig. 1, #30) adapt to induce a peristaltic movement (col. 2, lines 49-62).

It would have been obvious to one skilled in the art at the time of the invention to have included the cam of Moubayed in the peritoneal dialysis apparatus of Kamen, as modified by Neftel and Williams, in order to extend and retract the pump fingers (col. 4, lines 2-3) as explicitly taught by Moubayed.

9. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen, as modified by Neftel, Williams and Moubayed, as applied to claim 28 above, and further in view of U.S. Patent No. 2,684,829 to Rolland McFarland Jr. (McFarland).

In Reference to Claim 29

Kamen, as modified by Williams and Moubayed, teaches:

A system according to claim 28 (see rejection above) wherein said individual actuators are adapted to be actuated by fingers (Moubayed Fig. 1, #30)

But does not teach, the actuators are actuated by fingers clipped to the membrane

McFarland teaches:

which are clipped (Fig. 6, #39) to said membrane.

It would have been obvious to one skilled in the art at the time of the invention to have included the clip of McFarland in the peritoneal dialysis apparatus of Kamen, as modified by Neftel, Williams and Moubayed, in order to improve the diaphragm to extend diaphragm life and maintain proper mechanical action (col. 1, lines 30-34) as implicitly taught by McFarland.

10. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen, as modified by Neftel and Williams, as applied to claims 12 above, and further in view of U.S. Patent No. 4,530,647 to Fumio Uno (Uno).

In Reference to Claim 13

Kamen, as modified by Williams, teaches:

A system according to claim 12 (see rejection above) where said rollers (Williams col. 4, lines 53-56)

But does not teach a system where said rollers are of a conical shape in such a way as to be self inserted in the pump race, i.e. without any other mechanism.

Uno teaches:

are of a conical shape (Fig. 2, #5, 5') in such a way as to be self inserted in the pump race (col. 1, lines 42-44), i.e. without any other mechanism.

It would have been obvious to one skilled in the art at the time of the invention to have included the conical rollers of Uno in the peritoneal dialysis apparatus of Kamen, as modified by Neftel and Williams, in order to replace the pump tube due to wear out (col. 1, lines 62-63) as explicitly taught by Uno.

11. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen, as modified by Neftel and Williams, as applied to claims 12, 35-39, and 55 above, and further in view of U.S. Patent No. 5,840,069 to Reginald D. Robinson (Robinson).

In Reference to Claim 14

Kamen, as modified by Williams, teaches:

> A system according to claim 12 (see rejection above) where said rollers (Williams col. 4, lines 53-56)

But does not teach a system where said rollers are of a spherical shape.

Robinson teaches:

> are of a spherical shape (Fig. 1, #62, 63 & col. 2, lines 19-20).

It would have been obvious to one skilled in the art at the time of the invention to have used the spherical rollers of Robinson in the peritoneal dialysis apparatus of Kamen, as modified by Williams, in order to produce a highly accurate peristaltic pump and minimize the necessary machining (col. 1, lines 44-46) as explicitly taught by Robinson.

12. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen, as modified by Neftel, as applied to claim 17, in further view of U.S. Patent No. 5,478,211 to Dominiak et al. (Dominiak).

In Reference to Claim 18

Kamen, as modified by Neftel, teaches:

> A system according to claim 17 wherein said liquid pump (Fig. 8A, #P1, P2) is fixed to said liquid distribution system (Fig. 8A, #24 & col. 7, lines 43-46)

However, Kamen, as modified by Neftel, does not teach:

by vibration attenuation means in order to minimize the vibration on the liquid distribution system when the pump is operating.

Dominiak teaches:

by vibration attenuation means (col. 17, lines 29-32) in order to minimize the vibration on the liquid distribution system when the pump is operating.

It would have been obvious to one skilled in the art at the time of the invention to have included the vibration attenuation means of Dominiak in the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to increase patient comfort as implicitly taught by Dominiak.

13. Claims 31, 34, 46, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen, as modified by Neftel, as applied to claim 21, in further view of U.S. Patent No. 4,828,545 to Paul Epstein, et al. (Epstein).

In Reference to Claim 31

Kamen, as modified by Neftel, teaches:

A system according to claim 21 (see rejection above) wherein said membrane (Fig. 8, #59, 61)

However, Kamen, as modified by Neftel, does not teach:

contains protruding elements designed for a liquid tight connection between said hub chambers.

Epstein teaches:

contains protruding elements (Fig. 4C, #250, 262, 263) designed for a liquid tight connection between said hub chambers (col. 16, lines 42-46).

It would have been obvious to one skilled in the art at the time of the invention to have included the protruding elements of Epstein in the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to provide a seal to prevent fluid flow (col. 16, lines 45-46) as explicitly taught by Epstein.

In Reference to Claim 34

Kamen, as modified by Neftel, teaches:

> A system according to claim 21 (see rejection above) wherein said membrane (Fig. 8, #59, 61)

However, Kamen, as modified by Neftel, does not teach:

> is press-fitted along its external border to the liquid distribution system, the membrane being furthermore held by a frame.

Epstein teaches:

> is press-fitted (Fig. 4D, Fig. 4E, #198) along its external border to the liquid distribution system (Fig. 4A, #194), the membrane (Fig. 4C, #198) being furthermore held by a frame (Fig. 4E, #196).

It would have been obvious to one skilled in the art at the time of the invention to have included the press-fit and frame of Epstein in the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to create a "fluid tight sealing engagement" (col. 15, lines 44-45) as explicitly taught by Epstein.

In Reference to Claim 46

Kamen, as modified by Neftel, teaches:

A system according to claim 45 (see rejection above) wherein said molded frame (Fig. 13, #102)

However, Kamen, as modified by Neftel, does not teach:

is fixed to said liquid distribution system, e.g. by ultrasound, laser welding, gluing or thermal bonding.

Epstein teaches:

is fixed to said liquid distribution system (Fig. 4E, #196), e.g. by ultrasound, laser welding, gluing or thermal bonding (col. 16, lines 61-63).

It would have been obvious to one skilled in the art at the time of the invention to have included the fixed frame liquid distribution system of Epstein in the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to secure in fluid tight sealing engagement (col. 16, lines 62-63) as explicitly taught by Epstein.

In Reference to Claim 59

Kamen, as modified by Neftel, teaches:

Method according to claim 56 (see rejection above) … entering and exiting the liquid distribution system (Kamen Fig. 8A, #24)

However, Kamen, as modified by Neftel, does not teach:

consisting of sensing the liquid pressure entering and exiting … and, if necessary, correct the pump flow rate in accordance with the pressure difference.

Epstein teaches:

consisting of sensing the liquid pressure (Fig. 1, #40) ... and, if necessary, correct the pump flow rate in accordance with the pressure difference (col. 21, lines 7-10).

It would have been obvious to one skilled in the art at the time of the invention to have added the flow rate control method of Epstein in the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to detect a "variation between actual and intended infusate volume" (col. 3, lines 39-40) as explicitly taught by Epstein.

14. Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen, as modified by Neftel, as applied to claim 56 above, in further view of U.S. Patent No. 4,952,372 to Bernhard Huber (Huber).

In Reference to Claim 60

Kamen, as modified by Neftel, teaches:

Method according to claim 56 (see rejection above)

However, Kamen, as modified by Neftel, does not teach:

consisting in regulating the pump flow rate according to a known predetermined alteration of the flow rate by aging of the tubing.

Huber teaches:

consisting in regulating the pump flow rate according to a known predetermined alteration of the flow rate by aging of the tubing (col. 6, lines 16-20).

It would have been obvious to one skilled in the art at the time of the invention to have included the tubing age compensation method of Huber in the peritoneal dialysis

apparatus of Kamen, as modified by Neftel, in order that "delivery is independent of aging and external influences" (col. 6, lines 19-20) as explicitly taught by Huber.

15. Claims 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen, as modified by Neftel, as applied to claim 56 above, in further view of U.S. Patent No. 4,586,920 to Alan M. Peabody (Peabody).

In Reference to Claim 62

Kamen, as modified by Neftel, teaches:

Method according to claim 56 (see rejection above)

However, Kamen, as modified by Neftel, does not teach:

wherein the peritoneal volume filled during a cycle is a function of the intra-peritoneal pressure.

Peabody teaches:

wherein the peritoneal volume filled during a cycle is a function of the intra-peritoneal pressure (col. 5, lines 51-55).

It would have been obvious to one skilled in the art at the time of the invention to have included the pressure control method of Peabody in the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to increase dialysis efficiency as explicitly taught by Peabody (col. 2, lines 22-25).

In Reference to Claim 63

Kamen, as modified by Neftel, teaches:

Method according to claim 62 (see rejection above)

However, Kamen, as modified by Neftel, does not teach:

wherein the peritoneal cavity is partially emptied as soon as the pressure has reached a predefined threshold.

Peabody teaches:

wherein the peritoneal cavity is partially emptied as soon as the pressure has reached a predefined threshold (col. 5, lines 11-19).

It would have been obvious to one skilled in the art at the time of the invention to include the pressure control method of Peabody in the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to minimize the danger of infection as explicitly taught by Peabody (col. 2, lines 29-30).

16. Claims 22, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen, as modified by Neftel, as applied to claim 1 above, in further view of U.S. Patent No. 2,684,829 to Rolland McFarland Jr. (McFarland).

In Reference to Claim 22

Kamen, as modified by Neftel, teaches:

A system according to claim 1 (see rejection above) wherein each hub chamber (Fig. 8A, #F8, F9) is closed with an upper wall made of a flexible membrane (Fig. 8, #59, 61),

However, Kamen, as modified by Neftel, does not teach:

said membrane including clipping means adapted to clip elements such as valve actuating or finger elements.

McFarland teaches:

said membrane including clipping means (Fig. 6, #39) adapted to clip elements such as valve actuating (Fig. 6, #33) or finger elements.

It would have been obvious to one skilled in the art at the time of the invention to have added the clip elements of McFarland to the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to improve the diaphragm to extend diaphragm life and maintain proper mechanical action (col. 1, lines 30-34) as implicitly taught by McFarland.

In Reference to Claim 32

Kamen, as modified by Neftel, teaches:

A system according to claim 21 (see rejection above) wherein each of said valve elements (Fig. 8C, #V_N)

However, Kamen, as modified by Neftel, does not teach:

is designed to be clipped to an actuator (34), e.g. an electromagnetic actuator or a magnet, arranged above said membrane (13).

McFarland teaches:

is designed to be clipped (Fig. 6, #39) to an actuator (Kamen Fig. 13, #VA1), e.g. an electromagnetic actuator or a magnet, arranged above said membrane (Kamen Fig. 7).

It would have been obvious to one skilled in the art at the time of the invention to have included the clip of McFarland in the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to improve the diaphragm to extend diaphragm life and maintain proper mechanical action (col. 1, lines 30-34) as implicitly taught by McFarland.

In Reference to Claim 33

Kamen, as modified by Neftel, teaches:

A system according to claim 32 (see rejection above) wherein each of said valve elements (Fig. 8C, #V_N)

However, Kamen, as modified by Neftel, does not teach:

comprises a cavity designed to receive and hold the plunger of an actuator, said cavity having an height which substantially corresponds to at least the valve displacement.

McFarland teaches:

comprises a cavity (col. 4, lines 47-48) designed to receive and hold the plunger of an actuator (Fig. 6, #33), said cavity having an height which substantially corresponds to at least the valve displacement (col 4, lines 48-54).

It would have been obvious to one skilled in the art at the time of the invention to have added the cavity of McFarland in the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to improve the diaphragm to extend diaphragm life and maintain proper mechanical action (co1. 1, lines 30-34) as implicitly taught by McFarland.

Furthermore, it is inherent in the disclosure of McFarland that the cavity is at least the valve displacement because in order for the lower surface of the bar to conform "to the contour of the surface of weir 35 in order to hold the diaphragm in leak-proof relationship with the weir when in closed position" (col. 4, lines 50-54).

17. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen in view of McFarland.

In Reference to Claim 53

Kamen teaches:

> A system for performing fluid administration (col. 1, lines 8-9) on a patient comprising a flexible membrane (Fig. 8, #59, 61) forming a valve seat (Fig. 8C, #72)

However, Kamen does not teach:

> characterized by the fact that said membrane includes a clipping mechanism adapted to be reversibly attached to a moving actuator in such a way that the membrane movement can be controlled in a push and a pull operation mode.

McFarland teaches:

> characterized by the fact that said membrane includes a clipping mechanism (Fig. 6, #39) adapted to be reversibly (col. 4, lines 62-65) attached to a moving actuator (Fig. 6, #33) in such a way that the membrane movement can be controlled in a push and a pull operation mode (col. 5, lines 23-29, 62-66).

It would have been obvious to one skilled in the art at the time of the invention to have included the clipping mechanism of McFarland in the peritoneal dialysis apparatus of Kamen, as modified by Neftel, in order to improve the diaphragm to extend diaphragm life and maintain proper mechanical action (col. 1, lines 30-34) as implicitly taught by McFarland.

18. Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen in view of Neftel and McFarland as applied to claim 22 above, and further in view of European Patent Application Publication EP 1 195 171 A2 to Suzuki, Minoru et al. (Suzuki).

In Reference to Claim 23

Kamen, as modified by Neftel and McFarland, teaches:

A system according to claim 22 (see rejection above)

But does not teach a system wherein said membrane is molded.

Suzuki teaches wherein said membrane is molded (col. 9, lines 36-38).

It would have been obvious to one skilled in the art at the time of the invention to have used the molded membrane of Suzuki in the peritoneal dialysis apparatus of Kamen, as modified by Neftel and McFarland, in order to improve the quality of the cassette and reduce the cost (col. 9, lines 38-40) as explicitly taught by Suzuki.

In Reference to Claim 24

Kamen, as modified by Neftel and McFarland, teaches:

A system according to claim 23 (see rejection above) wherein said membrane is made out of any of the following materials: silicone or polyurethane.

But does not teach a system wherein said membrane is made out of any of the following materials: silicone or polyurethane.

Suzuki teaches wherein said membrane is made out of any of the following materials: silicone (col. 10, line 8) or polyurethane (col. 10, line 7).

It would have been obvious to one skilled in the art at the time of the invention to have chosen a material with particular properties, "a soft resin" (col. 9, line 56). See MPEP 2144.07.

In Reference to Claim 25

Kamen, as modified by Neftel and McFarland, teaches:

A system according to claim 24 (see rejection above) wherein said membrane includes liquid tight joints (Kamen col. 7, lines 40-42).

(10) Response to Argument

Applicant argues that there is no reason why a person skilled in the art would or could insert the Neftel peristaltic pump into the Kamen device in order to arrive at applicant's claimed invention (Appeal Brief pg. 14). This is not persuasive because the peristaltic pump of Neftel is a known type of pump, and one of ordinary skill would understand that a peristatic pump could be substituted for the membrane pump without destroying the functionality of the Kamen device, as the peristaltic pump can perform the same function of simulating gravity flow for peritoneal dialysis.

Applicant argues that the claimed invention requires a partial peristaltic pump that is separate from a liquid distribution system and Kamen's device requires two membrane pumps contained within a liquid distribution system (Appeal Brief pg 14.). This is not persuasive because the claims require "a liquid distribution system that is a cartridge and that is separate from said pump..." the pump of Kamen is separated by a wall from the liquid distribution system, furthermore the combination of Kamen, in view of Neftel, shows a partial peristaltic pump could be substituted for the membrane pumps of Kamen. Indeed, a peristaltic pump replacing the membrane pump of Kamen would require a wall or race to squeeze the tubing against, which would also separate the pump from the liquid distribution system.

Applicant argues that Kamen's system does not have the applicant's claimed unidirectional ports (Appeal Brief pgs. 15-16), this is not persuasive because the claim limitation states "wherein all ports of the liquid distribution system that communicate with the pump are

unidirectional such that liquid only flows in one direction" which lacks a recitation of structure that limits the function of the ports to only one direction. The ports of the Kamen cassette function such that fluid flows in one direction (col. 35, lines 4-12, 32-40) which shows that when valve V7 and V8 are opened in one direction during pumping.

In response to applicant's argument that there is no reasonably apparent way to use the alleged clipping mechanism in McFarland with the Kamen device (Appeal Brief pgs. 17-18), the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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